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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/001,737	12/31/1997	LEE MIZZEN	870109.408	7028

7590 01/02/2002

LEE CREWS PH.D
FISH & RICHARDSON PC
225 FRANKLIN STREET
BOSTON, MA 02110-2804

[REDACTED] EXAMINER

FIELDS, IESHA P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/001,737	MIZZEN ET AL.
	Examiner lesha P Fields	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-8, 19-24, 31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment received October 15, 2001(Paper No. 15) has been received and entered. Claims 3, 4, 19 and 13 were amended. Applicant's were subjected to a restriction requirement and elected Claims 2-8, 19-24, 31(Group II) and SEQ ID No.7. Consequently, the elected claims and SEQ ID No.7 were examined in the previous Office Action (Paper No 11) and are under examination in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 2-8 and 31 rejected under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments.
2. Claim 5 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicant's have asserted that the specification clearly describes the claimed invention and that the description is clearly presented and adequate.

Applicant's arguments have been carefully considered but not deemed persuasive.

As stated previously, claim 5 recites a nucleotide sequence that is identical to a segment comprising at least 25% of the contiguous nucleotide bases set forth in SEQ ID NO: 7. The specification and claim do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 7 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

3. Claims 3 and 7 rejected under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicants amendment to claim 3.

However, the rejection of dependent claims 19-24 and 31 is maintained because the rejection is now applicable to amended claim 4 which recites "high stringency" (similar vague and indefinite language previously recited in claim 3). One of skill in the art would be unable to determine the meets and bounds of such a limitation. For instance, what level of hybridization does the applicant intend? Without a clear

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definition as to what level of hybridization is intended by the applicant, one of skill in the art would be unable to replicate the claim

Claim Rejections - 35 USC § 102

4. Claims 4-5 rejected under 35 U.S.C. 102(b) as being anticipated by Birkett et al. is withdrawn in view of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

5. Claims 3-4 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Srivasta et al. in view of Hamel and Suzue et al. is withdrawn in view of Applicant's amendment to the claims.

However, claims 2, 9-10, 19-24 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Srivasta et al. in view of Hamel and Suzue et al. is maintained.

Applicant's have asserted that the claims recite specific SED ID NOs which are not disclosed in the prior art. Applicant's further assert that although heat shock proteins were known in the prior art, that there would be no motivation to isolate the nucleic acid disclosed by the applicant (i.e. the heat shock protein of *S. pyogenes*).

Applicant's arguments have been carefully considered but not deemed persuasive.

Claim 2 recites a nucleic acid molecule encoding a *Streptococcus Hsp60*. The claim does not recite a specific SED ID NO as the Applicant has asserted. Therefore a

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specific sequence need not be disclosed in the prior art. Claims 9-10, 19-24 and 31 are rejected because they depend on a rejected claim.

As stated previously, Srivasta et al. teach of methodologies for isolating Hsp60 polypeptides in several pathogenic organisms including bacteria. Srivasta et al. further teach of methods of making and using recombinant heat shock proteins.

Hamel et al teach of isolated nucleotide sequences encoding *Streptococcus* heat shock proteins derived from *Streptococcus pyogenes* and *Streptococcus pneumoniae* species.

Suzue et al teach that heat shock proteins when used as a subunit vaccine, stimulate protective immunity in animal models.

Given that 1) Srivasta et al. has taught of isolating Hsp60 polypeptides in pathogenic organisms and expressing the polypeptides in a suitable vector and that 2) Hamel et al. has taught of isolating the nucleotide sequences encoding Streptococcus heat shock proteins and that 3) Suzue et al. has taught that heat shock proteins when used as a subunit vaccine, stimulate protective immunity in animal models it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to isolate nucleic acid molecules encoding heat shock proteins (i.e. Hsp60, Hsp70, Hsp90) in *Streptococcus*.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

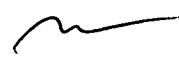
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

December 23, 2001


MARK NAVARRO
PRIMARY EXAMINER